

June 16, 1999

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Dockets Management Branch (HFA-305)  
JUN 23 1999  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Docket No. 99D-0557

This letter is directed toward the use of Nonhuman Primate Xenografts, these xenografts are dangerous and immoral.

While the FDA has implemented a ban on the transplantation of vital organs, cells, and tissue from nonhuman primates to humans due to "significant infectious disease risk," the agency has failed to admit or recognize the dangers posed by transplants from other species.

Pigs, have become the species of choice among the various companies vying for a piece of the animal organ market, pose an equally significant risk to human health. Pigs carry a number of unknown viruses that could jump from one species to another as a result of xenografts. Pigs can harbor swine influenza, Australian paramyxovirus; a novel strain of Hepatitis E, Japanese Encephalitis (JE), and the "Nipah" virus which has infected over 250 humans, killed 100, and led to the slaughter of millions of pigs in Malaysia. These dangers have led the British Government to place a moratorium on all xenografts.

The human immune system is designed to identify and reject foreign objects. Human-to-human transplants have relied on immunosuppressive drugs to control rejection of transplanted organs. Genetic differences make transplants from other species particularly noticeable to the human immune system. Even chimpanzees, our closest relatives, are six times as different from us as we are from each other, and the risk of rejecting a baboon organ is 25 times greater than for an unmatched human organ. In 1984, doctors at Loma Linda University in California transplanted a baboon heart into an infant born with serious heart defects. "Baby Fae"

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died 20 days later. There were three other options-all more promising than a xenograft-available to treat her condition.

Each xenograft procedure cost between \$250,000 and \$300,000 to perform. The University of Pittsburgh's experimental transplant program receives more than \$8 million each year in funding, largely through federal grants from the National Institute of Health. Meanwhile, many promising new treatments for AIDS and other life threatening diseases go unexplored because of lack of funding.

The Food and Drug Administration and the National Institutes of Health's policy on xenografts has transformed earth into a giant experimental laboratory in which every tax payer will be forced to participate in cruel, wasteful, and dangerous cross-species organ transplants. The tens of millions of dollars that have been wasted in the study of xenografts would be better spent on truly life-saving efforts to prevent and treat diseases, and they have failed to adequately promote human organ donations.

Please put a ban on xenotransplantation immediately.

Thank you for your time, and please consider what I have said!

Sincerely, Monica Jankowski

A handwritten signature in cursive script that reads "Monica Jankowski". The signature is written in dark ink and is positioned below the typed name.

Monica Jankowski  
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